

REMARKS/ARGUMENTS

Favorable reconsideration of this application as presently amended and in light of the following discussion is respectfully requested.

Claims 7, 8, 32, 51, 55-60, and 63-83 are presently active in this case. Claims 55-58 and 64 have been amended and Claims 65-83 have been added by the present amendment. No new matter has been added.

In the outstanding Office Action, claim 64 was objected to; claims 55 and 56 were rejected under 35 USC 102(b) as being anticipated by U.S. patent No. 4,653,513 to Dombrowski; and claims 57-60 were rejected under 35 USC 102(e) as being anticipated by U.S. patent No. 5,857,983 to Douglas et al.

Claims 7, 8, 32, 51, 63 and 64 were indicated as being allowable. Applicants acknowledge with appreciation the indication of allowable subject matter.

Claim 64 has been objected to. Applicants have amended claim 64 as proposed in the office action. No further objection is therefore anticipated.

Dombrowski et al Rejection

Dombrowski is directed to a blood sampling device which uses a needle to deeply pierce the skin. The objective of Dombrowski is to obtain blood (and interstitial fluid which is unavoidably withdrawn). It is distinguishable from the claimed invention in multiple ways.

First, Applicants respectfully submit that Dombrowski does not teach or suggest a device for forming a *hole*, or an open hole, in skin (a) by removing tissue so that fluids may be readily withdrawn from the created hole or (b) by stretching the skin in an area around a puncture in order to create an open hole. Dombrowski merely teaches piercing (i.e. cutting) the skin and applies a vacuum over a large area without stretching the skin. Consequently, (a) the tissue pierced by the lance in Dombrowski *closes* immediately upon piercing because

of the natural forces within the skin and (b) the effect of vacuum on withdrawal of fluids is substantially impeded in the Dombrowski device.

Furthermore, it is clear that Dombrowski is unconcerned with the problem of re-closure, because, by deeply piecing the skin, it can take advantage of the inherent blood pressure to urge blood out of the body, with substantially less vacuum than would be required for other biological fluid from shallow holes in the skin. Small or shallow holes that can be created with a laser or by using a lancet in combination with vacuum and stretching of the skin in the area adjacent to the hole, have the advantage of reduced pain and trauma.

The subject matter defined by claims 55 and 56 is patentably distinguishable. Applicants teach, by way of non-limiting examples, poration and ablation devices which *remove* tissue to actually create a hole or the use of a piercing in combination with stretching of the skin in the area adjacent to the hole as opposed to a mere piercing as taught by Dombrowski. Consequently, when the hole is created, it remains open and unobstructed by tissue which would otherwise collapse around it. An open hole is needed to maximize the effect of a vacuum or other pressure source, especially when it is desired to provide the least damage possible to the underlying tissues for blood withdrawal or when interstitial fluids (ISF) are sought. Tissue fluids, such as ISF are under low or no pressure and would be effectively blocked by Dombrowski's self sealing piercing.

Second, Dombrowski's use of vacuum is not a teaching of a vacuum system which can be applied to the more complex problem of creating an open hole for efficient blood or ISF withdrawal. The official action further asserts that Dombrowski discloses a vacuum system. Dombrowski appears to use cylinder 118 as its vacuum chamber. However, claims 55 and 56, as amended, define a vacuum pump configured to introduce a vacuum onto the area of skin so as to apply a stretching force to the skin to enhance-fluid flow from the skin. In Dombrowski, there is a vacuum created in the cylinder. There is no suggestion in that

disclosure that the skin is forced to stretch. Moreover, the Dombrowski vacuum appears to be applied to a large area and not to the area adjacent to an open hole as would be needed to create an open hole. See the figures of Dombrowski.

Thirdly, Dombrowski does not recognize a critical factor in withdrawing a sufficient amount of biological fluid to conduct an assay, namely *maintaining* the vacuum pressure at a desired pressure level. In Dombrowski, the pressure will necessarily rise suddenly as the spring actions are triggered and then drop, due to the spring action, leakage and as blood comes out of the wound. The loss of pressure cannot be restored or maintained in Dombrowski. Applicants respectively submit that Dombrowski cannot be used for a teaching of maintaining a desired pressure level as defined by the present claims.

Fourthly, Dombrowski does not teach use of a vacuum intended to cause the skin to stretch or bulge. Applicants concede that any vacuum applied to any surface will attempt to cause deflection, but any stretching useful for creating an open hole must be done in an area where the vacuum is focused adjacent to the point of puncture/ablation. In the present claims, the vacuum is introduced adjacent to the hole (claim 55) or in the vicinity of the hole, for example. Dombrowski fails to capitalize on the purpose of such deflection/stretching or bulging to enhance fluid withdrawal by maintaining an open hole.

Finally, the present claims call for a vacuum pump configured to maintain the vacuum at a desired level. Even if Dombrowski is interpreted as disclosing or suggesting a source of vacuum, Applicants submit that Dombrowski fails to teach or suggest a vacuum pump configured to maintain the vacuum at a desired level. Rather, Dombrowski merely discloses a *one-shot* vacuum action which has no control whatsoever. The Dombrowski device is not configured to control levels of the vacuum, let alone the collection of fluids.

For the foregoing reasons, Dombrowski is not believed to anticipate or render obvious the subject matter defined by claims 55 and 56 and the applicants respectfully ask that these claims be allowed

Douglas et al. Rejection

Claims 57-60 were rejected under 35 USC 102(e) as being anticipated by U.S. patent No. 5,857,983 to Douglas et al. Applicants submit that Douglas et al. merely teach applying a vacuum *through a piercing member* in order to draw fluid. See column 4 line 45: “*A suction is then applied to the **piercing element** to draw in body fluid from the incision and into a tube communicating with the **piercing element**.*” Thus the problem-solution presented and solved by Douglas et al. is different and inapplicable to the presently claimed invention. In effect, Douglas et al. use a needle as if it were a straw placed in a wound, provide a fixed flow path, and provide some degree of suction to force blood to flow in a hollow needle. Hence, the Douglas et al. disclosure is patentably distinct from the claimed invention.

Douglas et al. do not teach 1) creating an open hole by removing tissues (it only cuts a wound) or 2) applying stretching forces to the skin (it applies vacuum below the skin directly through the hollow needle). Moreover, even assuming there is a pump in Douglas et al., it lacks the control features of claim 57. Further regarding claim 57, the incision of Douglas et al. is not an open or unobstructed hole. This is clear because Douglas et al. teach “[s]imultaneously, the piercing element is moved within the incision in order to keep the incision open.” With the piercing member present, the incision is necessarily blocked or obstructed. In contradistinction thereto, for example, a laser or heat generated hole is intrinsically open or unobstructed because the tissue is vaporized and a lancet created hole, in which the area around the hole is subject to vacuum, necessarily bulges upward toward the source of the vacuum thus opening the hole.

Finally, column 4 line 24 of Douglas et al. states that “*A suction mechanism disposed on the housing creates a suction in the tube for drawing in body fluid **through the piercing element and into the tube.***” Hence, although Douglas et al. do use suction, the suction is not used to stretch the skin or to affect an area of the skin for the purpose of causing more fluid to be collected.

Clearly the technical problem solved by Douglas et al. does not lead one to the solution of the present invention, and the addition of Dombrowski, for reasons stated above, still lacks the teachings necessary to find the present invention.

For the foregoing reasons, Douglas et al. are not believed to anticipate or render obvious the subject matter defined by claims 57-60 and the applicants respectfully ask that those claims be allowed.

Newly Added Claims 65-83

Original claims 2, 3, 5, 6, 38, 52, 53, 61, and 62, were rejected under 35 USC 102(b) as being anticipated by U.S. patent No. 4,637,403 to Garcia et al., but their patentability over Garcia et al. was never argued and they were withdrawn in error. Applicants apologize for the previous omission. Newly added claims 65-75 are based on original claims 2-6, 38, 52-54, 61, and 62. These claims, as modified, are resubmitted herewith as new claims 65-75, but now with an analysis of the inapplicability of the Garcia et al. patent as follows.

The Garcia et al. patent is directed to a hand held system for glucose measurement. Garcia et al. call for a vacuum force to be produced “about a time period that the needle in penetrating the skin.” See the Garcia et al. abstract. The Garcia et al. system is clearly *not* a system which (1) uses vacuum to stretch the skin, (2) controls the pressure to maintain the vacuum at a desired level, or (3) applies a vacuum to the skin adjacent to the incision site.

Indeed, Garcia et al.’s use of vacuum seems almost incidental. In many respects, Garcia et al. is similar to Douglas et al. in that they use vacuum through a the needle rather

than directly on the skin. Needle 404 must be hollow in order for the Garcia et al. device to perform a colormetric test. The vacuum can be used to induce a small negative pressure effect simply as a means to move the blood along the hollow needle. Garcia et al. do not apply vacuum to the skin and therefore cannot induce the stretching needed to create an open hole in combination with a piercing element and does not disclose a method for creating an open hole through laser poration or heat. Applicants respectfully submit that Garcia et al. fail to anticipate or render obvious the subject matter defined by the newly added claims and request that these claims be allowed.

Original claims 4 and 54 were rejected over Garcia et al. in view of U.S. patent No. 5,746,217 to Erickson et al. Newly added claims 67 and 73 depend from claims 65 and 71, respectively, and provide that the biological fluid comprises interstitial fluid. Erickson et al. disclose an apparatus and method for collecting and measuring constituents in a sample of body fluid. Erickson et al. do not address the deficiencies of Garcia et al. *nor does it provide a teaching of how and why such a combination should be pursued.* That is, Erickson et al. do not teach forming a hole in biological tissue suitable for extracting a sample of biological fluid. Consequently, Garcia et al. are not believed to anticipate or render obvious the subject matter defined by claims 67 and 75 when considered alone or in combination with Erickson et al.

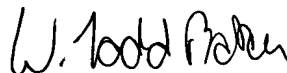
Request for Interview

The undersigned respectfully requests an interview with Examiner Marmor at his earliest convenience.

An early and favorable action is respectfully requested.

Respectfully submitted,

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